



Clinical Evaluation Summary

CES OSS K04

Össur - NOP4 knee

Warranty period - 3 Years

Weight Limit - 100kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The original version had worked well for many patients, but the brake mechanism had sometimes proved difficult to set up, especially on slightly more aggressive walkers. This would result in “popping” at toe off. Medi redesigned the knee and revised the set up instructions. The end result is a unit that is light, with a very effective brake and smooth swing phase control, both of which are easy to set up, with no sign of the problems sometimes found in the original version.

Indications

Low to medium/high activity patients. Medi activity level I to III
 Users of similar types of knees needing a lighter or more reliable unit
 Users of similar types of knees who want to upgrade the swing phase control, or who require a more sensitive brake
 Lower build height required*
 Shorter build length required*
 Primary patient, capable in the opinion of the M.D.T of using a free knee, but needing good stance control

Contraindication

Very active patients, above Medi activity level III
 Patients who currently make use of, need, or prefer a yielding hydraulic or geometric stance control knee
 Where a very short build height is required

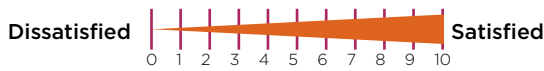
*These are comparative terms. Please check the technical manual for the exact dimensions.

Evaluation Patients

Patient Details

Patient 1	Transfemoral	95kg	46 year old male	Unknown	Sigam F
Patient 2	Transfemoral	75kg	44 year old female	Pharmacy Assistant	Sigam F
Patient 3	Transfemoral	73kg	43 year old male	Bank Clerk	Sigam F
Patient 4	Transfemoral	85kg	54 year old male	Engineer	Sigam F
Patient 5	Transfemoral	68kg	72 year old female	Retired	Sigam E
Patient 6	Transfemoral	75kg	51 year old male	Unemployed	Sigam E

Evaluation Result



Current Prescription

Patient 1	Blatchfords ESK/PSPC
Patient 2	Original Medi NOP4 on a quadrilateral socket with Seal-In liner and a Multiflex foot
Patient 3	Original Medi NOP4 on a quadrilateral socket, TES belt and CPI Trés foot
Patient 4	Ortho Europe Sensor knee, "H" type suction socket and a Multiflex foot
Patient 5	Original NOP4 on a quadrilateral socket, with TES belt and CPI Accent foot
Patient 6	Blatchfords ESK/PSPC and a Multiflex foot

Prosthetist's Comments

Patient 1 - The prosthetist's only comments were that the knee was easy to fit, align and adjust, with easy to understand technical literature. It has required no further adjustment or maintenance in six months of use.

Patient 2 - The prosthetist had problems with the original NOP4 and had been unable to stop the brake "popping" at toe off, though he had achieved it eventually. He found the new version of the knee much simpler to adjust and feels the patient, who was already an aggressive walker, hence the problems with the old unit, was now even more aggressive, but with no sign of the problems recurring. He also found the swing phase simple to set up.

Patient 3 - The patient was chosen to trial the new version of the NOP4 since the original NOP4 he had been provided with had developed a fault after a short period of use. This was the problem of "popping" at toe off. To try and prevent this, the brake sensitivity had been reduced to the point where it was inadequate.

The new version, which had been designed to overcome this problem, was fitted, but unfortunately it developed a noise after the patient fell off a dinghy into the sea!! The knee was replaced and the socket also had to be remade and the alignment was improved at the same time. Three months later and the knee was still silent and the brake still effective, but without any "popping".

Patient 4 - A long time user of a Blatchford's ESK, this gentleman had become rather dependant on a weight activated stabilized knee and was struggling a little with the hydraulic yielding option he was currently using. The NOP4 was prescribed to redress the situation.

Patient 5 - The original NOP4 had been prescribed it as a replacement for a worn out Endolite ESK/PSPC, in an attempt to reduce the weight of the prosthesis and improve the stance stability for this long time user, who was becoming a little frailer. The unit had been sent for refurbishment, due to ML play and had been upgraded to the new version.

Patient 6 - The prosthetist was presented with a patient who had lost confidence in his current prosthesis, but seemed fit enough to be able to make use of a free knee. The NOP4 was chosen, since it was similar to what the patient had already used, but could be set up to be very stable in the stance phase. No problems were experienced in setting up the knee to provide this stability, without compromising the swing phase.

Patient's Comments

Patient 1 - The patient rated his current knee at 2. Having had the NOP4 fitted he scored it 3 immediately, and found no fault with the unit, being most pleased with the fact that it had not required any attention in six months, but its function had remained the same.

Patient 2 - The patient declined to make any comment on the knee, since she had found the original version good and hadn't noticed any improvement in her gait with the new version, though her prosthetist felt that her confidence in the prosthesis had increased.

Patient 3 - The patient was clearly disappointed with the first knee he was provided with (original NOP4) and scored it -3. He acknowledged that the replacement functioned well and three months after the remake of the socket, said he had much more confidence in the prosthesis, stating the brake was strong and silent, with no "popping", but failed to award it a score, commenting only that his "friends had noticed an improvement in his gait".

Patient 4 - A man of few words and extremes of opinion, he stated that he found the Sensor knee too heavy and found it "hard to have faith in". He admitted he didn't like not having a stabilizing unit and therefore scored this current limb -4. He found the NOP4 lighter and he could walk further on it and scored it 5. Positive responses were made to all the questions regarding the knee's function and also the question regarding whether the knee had helped him undertake additional sporting or recreational activities, though he didn't comment as to what they were.

Patient 5 - The new version of the NOP4 has proven to be even better than the original version, since it has not required any maintenance, nor has it developed any ML play. The patient feels there is no difference in the function of the knee unit, but is finding it more difficult as her physical strength seems to be decreasing further. Her prosthetist feels that some improvements could be made and is refitting the socket to accommodate a small change in the residual limb volume and slight increase in hip flexion, incorporating the necessary anterior shift to ensure the weight line doesn't compromise the function of the knee.

Patient 6 - The patient quickly regained confidence after a couple of sessions of physiotherapy. His gait, which had become compromised by his loss of confidence and the resultant restriction of his hip mobility, hadn't improved significantly, but the patient has declared himself to be "much happier now".

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